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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,047	11/21/2003	Luke V. Schneider	020444-000110US	5048

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EXAMINER

KIM, YOUNG J

ART UNIT PAPER NUMBER

1637

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/721,047

Applicant(s)

SCHNEIDER ET AL.

Examiner

Young J. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 28 is/are rejected.
- 7) ☒ Claim(s) 22-30 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/21/2003</u> . | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Preliminary Remark

Claims 1-21 have been canceled by Applicants' preliminary amendment.¹

Information Disclosure Statement

The IDS received on November 21, 2003 is acknowledged.

A signed copy of the PTO-1449 is attached hereto.

Drawings

The drawings received on November 21, 2003 are acceptable.

Priority

In the preliminary amendment received on November 21, 2003, the specification has been amended to include information of application which are "related" to the instant application. It has been determined that the instant application is not claiming priority to the related application and the only application providing the benefit under 35 U.S.C. 119(e) and 120 are those which were cited in the ADS (Application Data Sheet).

Specification

The instant specification contains a string of contiguous amino acid residues which are more than 4 residues in length without a SEQ ID Identifier (page 11, line 4). Applicants are requested to comply with the requirement of 37 CFR 1.821 through 1.825.

Oath/Declaration

The oath/declaration is defective for the following reasons.

On page 60, lines 5-10 states the below:

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In some instances, the proteins separated by the methods of the invention are subjected to further analysis by mass spectroscopy. In such instances, particular labels can be utilized to enhance separation of mass fragments into certain parts of the mass spectrum. Suitable labels in such methods are set forth more fully in copending application number _____, entitled Methods for Protein Sequencing, having attorney docket number 020444-000300US, filed on the same date as the current application. This application is incorporated herein by reference in its entirety.

The preliminary amendment received on November 21, 2003, however, amends the above section of the specification as reproduced below:

Please replace the paragraph beginning on page 60, line 1 with the following paragraph:

--In some instances, the proteins separated by the methods of the invention are subjected to further analysis by mass spectroscopy. In such instances, particular labels can be utilized to enhance separation of mass fragments into certain parts of the mass spectrum. Suitable labels in such methods are set forth more fully in U.S. Patent Application Serial No. 09/513,395 (now U.S. Patent No. 6,379,971) filed on February 25, 2000. This application is incorporated herein by reference in its entirety.--

It should be noted that U.S. Patent Application Serial No. 09/513,395, has the attorney docket no. 20444-000200US, which is clearly different from the application incorporated by reference in the specification as originally filed. Since the amendment incorporates by reference to a different application than that which was originally incorporated (by reference), the amendment constitutes new matter, and the oath is defective for not identifying the instant application as being a CIP of its parent, 09/513,907.

Claim Objections

Claim 22 is objected to missing a conjunction, "and" after step (iii), so as to render complete the steps involved in the method.

¹ Claims 1-13 were canceled in the preliminary amendment received on November 21, 2003; claims 14-21 were canceled in a subsequent preliminary amendment received on December 23, 2003.

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Claim 22 recites the term, "mass spectrographic." It appears that this is a typographical error as the specification, throughout, recites the term, "mass spectrometric" (*see* for example, page 67, line 13). Claims 23-30 are objected to by way of their dependency on claim 22.

Correction is suggested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is indefinite for reciting the phrase, "determining the separation coordinates of said plurality of eluted intact protein species," because it is unclear what is meant by the "separation coordinates."

Clarification is requested.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Tang et al. (U.S. Patent No. 6,393,367 B1, issued May 21, 2002) evidences the digestion of proteins (proteolytic or chemical) into peptide fragments prior to subjecting them for mass spectrometry analysis (*see* Figure 1; column 1, line 20; column 6, lines 10-20; column 8, lines 1-

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9), which is different from the claimed method which involves subjecting intact peptide species to mass spectrometric analysis.

Mann et al. (Analytical Chemistry, December 1994, vol. 66, no. 24, pages 4390-4399; IDS ref # AM), discloses a method of identifying peptides based on peptide sequence tags (Abstract; page 4390, 2nd column, 2nd paragraph and 3rd paragraph), which can be as short as two amino acids (3rd paragraph). Mann et al. generate peptide sequence tags based on MS/MS (mass spectrometry/mass spectrometry, but employs peptides which are produced from digested protein (see page 4392, 1st column, 4th paragraph), which is different from the claimed method which involves subjecting intact peptide species to mass spectrometric analysis.

Inquiries

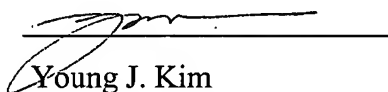
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE

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SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Patent Examiner
Art Unit 1637
9/16/2005

yjk

YOUNG J. KIM
PATENT EXAMINER